FDA 510(k) Premarket Notification

K260289 Perfect-O Ostial Positioning Catheter

CLEARED

Jun 5, 2026
127 days to decision

K260289 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k260289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 29, 2026
Decision date	Jun 5, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Balosmark, Inc.**
Location	Kalamazoo, MI, US
Contact	Tim Fischell
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Gateway Medical Consulting Services, LLC**
Contact	Nancy Frame

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov